

AMENDMENTS TO THE CLAIMS:

1. – 30. (Canceled)

31. **(Currently Amended)** A needleless injection device, comprising
a casing;

a cartridge containing a medicament for injection and an orifice at one end thereof through which the medicament is driven for injection through a patient's skin;

a drive mechanism which upon actuation applies force to the medicament, forcing the medicament out of the orifice and through the patient's skin;

a trigger mechanism which actuates the drive mechanism;

a safety mechanism which, in a first configuration, prevents the trigger mechanism from actuating the drive mechanism and in a second configuration allows trigger mechanism to actuate the drive mechanism; and

an actuator ~~mechanism~~ lever which moves the safety mechanism from its first configuration into its second configuration;

wherein the actuator mechanism comprises a portion extending outside of the casing which portion is accessible to a user and which when the portion is moved by the user the movement brings the safety mechanism into its second configuration.

32. **(Canceled)**

33. **(Previously Presented)** The device of claim 31, wherein the safety mechanism in its first configuration prevents the trigger mechanism from moving.

34. **(Canceled)**

35. **(Currently Amended)** The device of claim 31, wherein the actuator ~~mechanism~~ lever is comprised of a component which applies a pulling force to the safety mechanism to pull the safety mechanism from its first configuration into its second configuration.

36. **(Currently Amended)** The device of claim **31 34**, further comprising:

a retaining mechanism which retains the safety mechanism of an enclosed injection device in its second configuration after the safety mechanism has been brought into its second configuration.

37. **(Previously Presented)** The device of claim 33, wherein the safety mechanism comprises an obstructer portion which in the first configuration obstructs, and in the second configuration allows, movement of the trigger mechanism.

38. **(Previously Presented)** The device of claim 37, wherein the safety mechanism comprises a collar shaped to surround a portion of the injection device, the collar is moveable from its first collar configuration into its second collar configuration in a direction generally perpendicular to a direction in which the medicament exits the orifice, the collar comprising an obstructer portion.

39. **(Previously Presented)** The device of claim 38, wherein the trigger mechanism is comprised of two moveable upper and lower sleeve portions which on relative movement allow the drive mechanism to act, and the safety mechanism comprises an obstructer portion which in its first configuration obstructs, and in its second configuration allows, the relative movement of the sleeve portions.

40. **(Previously Presented)** The device of claim 39, wherein the safety mechanism comprises an obstructer portion which is brought from its first configuration to its second configuration by a movement of the obstructer portion in a direction perpendicular to a direction of relative movement of the two sleeve portions.

41. **(Currently Amended)** A combination comprising:

a casing which partially encloses a needleless injection device;

wherein the needleless injection device comprises:

a cartridge containing a medicament for injection and an orifice at one end thereof through which the medicament is driven for injection through a patient's skin;

a drive mechanism which upon actuation applies force to the medicament, forcing the medicament out of the orifice and through the patient's skin;

a trigger mechanism which actuates the drive mechanism;
a safety mechanism which, in a first configuration, prevents the trigger mechanism from actuating the drive mechanism, and, in a second configuration, allows the trigger mechanism to actuate the drive mechanism; and
a break-off tip which encloses the cartridge orifice prior to being broken off **the break-off tip configured such that breaking off the break-off tip irreversibly exposes an actuator for the safety mechanism.**

42. (Previously Presented) The combination of claim 41, wherein the casing may be broken off to provide for sequential operation of the needleless injection device.

43. (Previously Presented) The combination of claim 42, wherein the sequential operation provides for (a) breaking off the break-off tip; and (b) placing the safety mechanism in the second position.

44. **(Canceled)**

45. (Previously Presented) The combination of claim 43, wherein the casing comprises moveable first and second casing components, a first casing component adapted to hold the injection device, and a second casing component adapted to bear upon the break-off tip as a result of relative motion of the first and second components to apply a force thereto causing the break-off tip to break off from an injection device enclosed within the casing.

46. (Previously Presented) The combination of claim 45, wherein the first casing component is elongated with an opening at a first end.

47. (Previously Presented) The combination of claim 46, wherein the first casing component is elongated along a longitudinal axis, and wherein the second casing component is designed to apply a rotary motion relative to the first portion so as to bear on the break-off tip of a container held by the first casing portion, and to apply a twisting shearing force to the frangible joint between the break-off tip and the container.

48. (Previously Presented) The combination of claim 47, wherein the rotary motion is chosen from:

transverse to the longitudinal axis;

perpendicular to this longitudinal axis;

coaxial with the longitudinal axis;

about a rotation axis parallel to but non-coaxial with this longitudinal axis;

about a rotation axis at a non-zero angle to the longitudinal axis.

49. (Previously Presented) The combination of claim 48, wherein the rotary motion is about a rotation axis at a non-zero angle to the longitudinal axis.

50. (Previously Presented) The combination of claim 45, wherein the second casing component comprises a cover portion over the actuator for the safety mechanism which prevents operation of the actuator for the safety mechanism until the cover portion is removed.

51. (Currently Amended) The combination of claim ~~42~~ **[44]**, wherein the actuator for the safety mechanism moves the safety mechanism from its first configuration to its second configuration.

52. (Previously Presented) The combination of claim 51, wherein the trigger mechanism moves the safety means from its first configuration to its second configuration by pulling.

53. (Previously Presented) The combination of claim 52, wherein the safety mechanism comprises an obstracter portion which functions to obstruct movement of a portion of the injection device which is essential for operation.

54. (Previously Presented) The injection device of claim 31, wherein the drive mechanism comprises a compressed gas cylinder.

55. (Currently Amended) The combination of claim **41** ~~[[44]]~~, wherein the casing comprises a first casing sub-part and a second casing sub-part which fit together by a method chosen from, a tight friction fit, and a snap-fit fit.

56. (Currently Amended) A needleless injector device, comprising:

a cartridge containing a medicament for injection and an orifice at one end thereof through which the medicament is driven for injection through a patient's skin;

a drive mechanism which upon actuation applies force to the medicament, forcing the medicament out of the orifice and through the patient's skin;

a trigger mechanism which actuates the drive mechanism;

a safety mechanism which in a first configuration prevents movement of the trigger mechanism and in a second configuration allows movement of the trigger mechanism; and

a casing which encloses the drive mechanism, the casing comprising a ~~break-away part which when removed~~ **break-off tip configured such that breaking off the break-off tip irreversibly** exposes both the safety mechanism and the orifice through which the medicament is driven for injection through a patient's skin.